

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

CONSUELO CARDENAS, TERRY
PAULSEN, MAGDALYN DUSTIN, and
SUZANNE PRESTON

Plaintiffs,

v.

ABBOTT LABORATORIES, TAKEDA
PHARMACEUTICALS OF NORTH AMERICA,
INC., a wholly owned subsidiary of TAKEDA
CHEMICAL INDUSTRIES, LTD. and TAP
PHARMACEUTICAL PRODUCTS, INC.

Defendants.

Case No. 11 C 4860

Judge Joan B. Gottschall

MEMORANDUM OPINION & ORDER

This case comes to the court following transfer from the United States District Court for the Southern District of New York. Before the case was transferred, Plaintiffs filed an amended complaint alleging that they were harmed as a result of their use of Lupron Depot® (leuprolide acetate, or “Lupron”), a drug used to treat, *inter alia*, prostate cancer and endometriosis. Defendants (including Takeda Chemical Industries, Ltd., (“TCI”) no longer a party¹) moved to dismiss the complaint for failure to state a claim, improper venue, and lack of personal jurisdiction. The court analyzed the propriety of transfer under 28 U.S.C. § 1404(a) and concluded that transfer to this jurisdiction was appropriate. The dismissal of TCI and the transfer cured the venue and personal jurisdiction objections; thus, although the motion to dismiss remains pending, the only issue before this court is whether Plaintiffs’ amended complaint states a claim or should

¹ The court dismissed TCI because it was not served with process and because Plaintiffs moved to dismiss it as a party. It had been improperly named in the complaint as Takeda Chemical Industries, Inc.

be dismissed. For the reasons set forth below, this court grants the motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), but will grant Plaintiffs leave to file a second amended complaint.

I.BACKGROUND²

Cardenas (a California resident) and Paulsen (a Georgia resident) initially filed their complaint in the District Court for the Eastern District of New York, alleging that they had received Lupron injections on a number of occasions. According to their complaint, Abbott Laboratories (“Abbott”), together with Takeda Pharmaceuticals of North America (“Takeda”), created TAP Pharmaceutical Products, Inc. (“TAP”)³ as a joint venture with the goal of developing and marketing pharmaceutical products, including Lupron. Lupron was developed around 1985, and received approval from the Food and Drug Administration (“FDA”) for the palliative treatment of prostate cancer in 1989. Lupron was approved to treat endometriosis in 1990.

In April 1998, TAP notified FDA that there were concerns because more than one-third of the women taking Lupron in a study did not “demonstrate either partial reversibility” or a “trend toward return” of bone mass in the six months after the women ceased taking Lupron. In 2001, FDA approved the use of a progestin-based hormone replacement, norethindrone, as an “add-back therapy” to counteract the bone-depleting effects of the drug. But despite TAP’s knowledge of the bone loss issue, it did not take corrective action, give adequate warning, or take Lupron off the market. Instead, Defendants made affirmative claims—both to the medical profession and the general

² As this is a motion to dismiss under Rule 12(b)(6), all well-pleaded factual allegations in the complaint are taken as true; thus, the facts herein are those alleged by Plaintiffs unless otherwise noted.

³ TAP was dissolved as a corporation in May 2008.

public—that Lupron was safe and efficacious for women with gynecological problems such as endometriosis.

Cardenas and Paulsen filed their complaint in the Eastern District of New York, alleging seven counts against Defendants, including negligence, strict products liability, failure to warn, breach of express warranty, breach of implied warranty, fraudulent misrepresentation, and negligent misrepresentation. They sought \$5,000,000 in compensatory damages and \$5,000,000 in punitive damages. In a motion requesting a pre-motion conference, Defendants raised many of the same venue objections later asserted as part of their motion to dismiss. Cardenas and Paulsen responded via letter, arguing that venue was proper in that judicial district. Thereafter, Plaintiffs filed the amended complaint. That complaint appears to assert roughly the same underlying facts and counts, but adds two new plaintiffs: Magdalyn Dustin (a New York resident) and Suzanne Preston (a New Jersey resident).

About two weeks later, the case was transferred from the Eastern District of New York to the Southern District. Defendants filed their motion to dismiss in the Southern District of New York, and that court transferred the case here, thereby resolving the personal jurisdiction and venue objections raised in the motion. Therefore, the only issue before this court is whether Plaintiffs failed to state a claim upon which relief can be granted. Although Defendants briefed this issue for the Southern District of New York, and therefore relied largely on New York or Second Circuit precedent, the court has agreed to take the pleadings under consideration “as is” and will apply appropriate state law or Seventh Circuit precedent where applicable.

II. DISCUSSION

A. Standard of Review

Under Federal Rule of Civil Procedure 12(b)(6), the defendant may seek to dismiss the case if the plaintiff “fail[s] to state a claim upon which relief can be granted.” The court accepts as true all well-pleaded facts and draws all reasonable inferences in favor of the plaintiff. *Stayart v. Yahoo! Inc.*, 623 F.3d 436, 438 (7th Cir. 2010). But although Federal Rule of Civil Procedure 8(a) only requires the complaint to contain “a short and plain statement of the claim showing that the pleader is entitled to relief,” nonetheless the complaint must include “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The relevant question is whether the complaint includes enough factual allegations to “raise a right to relief above the speculative level.” *Id.* In other words, to survive a motion to dismiss post-*Twombly*, “‘the plaintiff must give enough details about the subject-matter of the case to present a story that holds together,’ and the question the court should ask is ‘*could* these things have happened, not *did* they happen.’” *Estate of Davis v. Wells Fargo Bank*, 633 F.3d 529, 533 (7th Cir. 2011) (quoting *Swanson v. Citibank, N.A.*, 614 F.3d 400, 404-05 (7th Cir. 2010)).

B. Analysis

Defendants raise a variety of issues with Plaintiffs’ amended complaint. First, they state that the amended complaint was filed outside the time set forth in Federal Rule of Civil Procedure 15(a)(1), and that Plaintiffs failed to obtain leave of court prior to amending the pleading. Second, Defendants argue that the amended complaint fails to satisfy the *Twombly* standard because the complaint lacks any facts regarding Plaintiffs’ use of Lupron, Plaintiffs’ diagnoses, Plaintiffs’ physicians’ decision to prescribe Lupron,

the number of times and the timeframe during which Plaintiffs used Lupron, the injuries alleged, and when those injuries occurred. Further, Defendants claim they have been lumped together in such a way that it is impossible to glean which defendant is allegedly culpable for any particular action. In addition, they argue that certain of the claims rely solely on boilerplate language and do not identify the specific actions at issue; for example, no particular statement is set forth as being a misrepresentation. Finally—based on Abbott’s own investigation—Defendants claim that Plaintiffs’ allegations are barred by the relevant state statutes of limitations.

For their part, Plaintiffs argue that they have pleaded sufficient facts to survive a *Twombly* challenge. They also state that the circumstances surrounding their treatment with Lupron are not “elements of their causes of action” and thus they had no need to include that type of information in their complaint. Should the court require such information, however, Plaintiffs have attached various affidavits as exhibits and urge the court to read the affidavits “in conjunction with the Amended Complaint” to determine the sufficiency of that pleading. Finally, as an alternative to the alternative, Plaintiffs move for leave to file a second amended complaint.

1. Documents and Facts Outside of the Pleadings

As a preliminary matter, Plaintiffs and Defendants both attempt to direct the court’s attention to facts not properly set forth in the pleadings: Plaintiffs have attempted to cure any perceived deficiencies in the amended complaint by filing various affidavits and supplemental exhibits, while Defendants represent in their motion that they have uncovered certain facts with respect to Plaintiffs’ use of Lupron that support dismissal. On a motion to dismiss under Rule 12(b)(6), however, the court will not consider matters

beyond the pleadings unless it wishes to convert the motion into one for summary judgment and provide the parties “a reasonable opportunity to represent all the material that is pertinent to the motion.” Fed. R. Civ. P. 12(d); *see McCready v. eBay, Inc.*, 453 F.3d 882, 891-92 (7th Cir. 2006) (noting that typically a court must convert a motion to dismiss into one for summary judgment if it wishes to evaluate documents outside of the complaint). The court does not intend to convert this motion to dismiss into a motion for summary judgment. Moreover, because the documents at issue are not of the type considered to be part of the pleadings, *see McCready*, 453 F.3d at 891 (“From this rule, we have concluded ‘documents attached to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff’s complaint and are central to his claim.’”) (quoting *188 LLC v. Trinity Indus., Inc.*, 300 F.3d 730, 735 (7th Cir. 2002)), nor are they of the type for which judicial notice is appropriate, *see 520 South Mich. Ave. Assocs., Ltd. v. Shannon*, 549 F.3d 1119, 1138 n.14 (7th Cir. 2008) (“A court may ‘take judicial notice of historical documents, documents contained in the public record, and reports of administrative bodies.’”) (quoting *Menominee Indian Tribe of Wis. v. Thompson*, 161 F.3d 449, 456 (7th Cir. 1998)), the court declines to consider facts beyond those set forth in the amended complaint.

2. The First Amended Complaint

The parties disagree as to whether the amended complaint was properly filed. Plaintiffs filed their initial complaint on April 20, 2010; in response, Defendants filed a letter seeking a conference on June 2, 2010, noting that they intended to move for dismissal under Rule 12(b)(3) and seeking an extension of time in which to answer or otherwise plead. Plaintiffs filed the amended complaint on July 16, 2010, more than

twenty-one days after serving their first complaint but before any responsive pleading or motion had been served. Defendants' request for a pre-motion conference was granted, and the conference was held on July 30, 2010. After the conference, the court transferred the case to the Southern District of New York; at the same time, the court also granted Defendants' request for an extension of time until after the parties held an initial conference with the transferee court. Once the case was transferred, Defendants responded by filing the motion to dismiss presently under consideration.

Defendants have suffered no prejudice as a result of the first amended complaint. Defendants had notice of the changes to Plaintiffs' claims well before Defendants moved to dismiss—in fact, Defendants based their motion to dismiss on the amended complaint. In any event, the only difference between the two complaints seems to be the addition of Dustin and Preston as plaintiffs. This difference does not affect the court's analysis, making it immaterial which complaint is considered active for purposes of this opinion. Further, as discussed below, the court is granting Plaintiffs leave to file a second amended complaint, which will have the effect of superseding all earlier pleadings. *See Kelley v. Crosfield Catalysts*, 135 F.3d 1202, 1204 (7th Cir. 1998) ("It is well-established that an amended pleading supersedes the original pleading; facts not incorporated into the amended pleading are considered *functus officio*."). As a result, the propriety of the first amended complaint is of no import.

3. Rule 12(b)(6)

Finally, turning to whether Plaintiffs have stated a claim that survives a motion to dismiss, Plaintiffs concede that the only facts they provide with respect to themselves are their states of residence and that they received Lupron injections "on several occasions."

As Defendants note, this limited amount of information provides them no ability to mount an effective affirmative defense based on the applicable statutes of limitations. Illinois has a two-year statute of limitations for personal injury actions, *see* 735 Ill. Comp. Stat. § 13-202, and a “borrowing provision” which dictates that “[w]hen a cause of action has arisen in [another state] . . . and, by the laws thereof, an action thereon cannot be maintained by reason of the lapse of time, an action thereon shall not be maintained in this State,” *see* 735 Ill. Comp. Stat. § 13-210. But Defendants seem to forget that under Rule 8, “a complaint need not anticipate or overcome affirmative defenses,” and “[a]s a result, a federal complaint does not fail to state a claim simply because it omits facts that would defeat a statute of limitations defense.” *Hollander v. Brown*, 457 F.3d 688, 691 n.1 (7th Cir. 2006) (citing *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004)).

Still, the court agrees that these allegations do not suffice to put Defendants on notice of the claims against them. With one exception (discussed below), Plaintiffs provide sufficient information to support their claims with respect to *Defendants’* acts; it is Plaintiffs’ acts and injuries that remain a mystery. Plaintiffs are obliged to give “enough details about the subject-matter of the case to present a story that holds together,” *Estate of Davis*, 633 F.3d at 533, and with nothing but the fact that Plaintiffs received Lupron injections “on several occasions,” the court cannot evaluate whether these claims hold water. For instance, the complaint does not make clear whether Plaintiffs are women, nor does it establish whether Lupron was prescribed to Plaintiffs for endometriosis, for prostate cancer, or for some off-label use. Moreover, these are the types of facts that are particularly within Plaintiffs’ control. Plaintiffs are not, however,

required to provide detailed information such as their physicians' decision to prescribe Lupron, the number of times they received Lupron injections, or the particularities of their alleged injuries at this stage. They only need to allege enough facts to push their claims into "plausible" territory. *See Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009).

In addition to putting some minimal amount of flesh on these bare-bones allegations, Plaintiffs must also provide additional facts to support their fraudulent misrepresentation claim. While negligent misrepresentation claims are not subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b), fraudulent misrepresentation claims are. *Compare Tricontinental Indus., Ltd. v. Pricewaterhouse Coopers, LLP*, 475 F.3d 824, 833 (7th Cir. 2007) ("We therefore must examine the necessary elements of a negligent misrepresentation claim under Illinois law. This claim is *not* governed by the heightened pleading standard of Rule 9(b).") *with Petrakopoulou v. DHR Int'l, Inc.*, 660 F. Supp. 2d 935, 937 (N.D. Ill. 2009) ("It is well-settled that claims for fraudulent misrepresentation are subject to Rule 9(b)'s heightened pleading standard.").

Rule 9(b) requires that a party "state with particularity the circumstances constituting fraud or mistake," meaning that "facts such as 'the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff' [must] be alleged in detail.'" *Hefferman v. Bass*, 467 F.3d 596, 601 (7th Cir. 2006) (quoting *Bankers Trust Co. v. Old Republic Ins. Co.*, 959 F.2d 677, 683 (7th Cir. 1992)). Here, Plaintiffs' fraudulent misrepresentation claim does not satisfy that standard. Plaintiffs have alleged that "[a]t all relevant times, the Defendants, jointly, severally, acting in

concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, made false and fraudulent representations to the medical community and to users of Lupron, including but not limited to that Lupron had been tested and found to be a safe and effective drug for, among other things, the treatment of endometriosis.” (See First Am. Compl. ¶ 64.) This is both too much—the allegation would include numerous unnamed actors and actions—and not enough. Because Plaintiffs fail to provide the “who, what, when, where, and how” of the fraud with specificity, the fraudulent misrepresentation claim cannot stand. *See Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 441-42 (7th Cir. 2011) (quoting *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009)).

III. CONCLUSION

For the reasons stated above, the court grants Defendants’ motion to dismiss, and grants Plaintiffs leave to file a second amended complaint.

ENTER:

/s/
JOAN B. GOTTSCHALL
United States District Judge

DATED: October 7, 2011